UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS	Judge Patti B. Saris

DEFENDANT AMGEN INC.'S MOTION FOR A CONTINUED LIMITED STAY OF DISCOVERY PENDING RULING ON ITS INDIVIDUAL MOTION TO DISMISS THE AMCC

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The stay of discovery should be continued as to Amgen Inc. pending the Court's consideration and ruling on Amgen's individual motion to dismiss the Amended Master Consolidated Complaint ("the AMCC"). Even a cursory reading of the AMCC underscores the absence of any good faith factual basis for dragging Amgen into this case. The enormously burdensome – and ultimately unnecessary – cost of requiring Amgen to respond to discovery at this juncture, together with the lack of any prejudice to plaintiffs, and consistent with this Court's prior rulings, plainly counsel in favor of continuing the stay of discovery previously ordered by the Court as to Amgen.

Argument

At the conclusion of the November 21, 2003, hearing on the motions to dismiss the AMCC, the Court ordered that discovery should proceed as to non-multiple-source, Medicare Part B reimbursed drugs for which the plaintiffs have alleged a purchaser. *See* 11/21/03 Hearing Tr. at 117 (relevant portions of which are attached hereto as Exhibit 1). The Court's ruling subjects three of the six Amgen products named in the AMCC to anticipated broad-ranging discovery. [1]

The stay of discovery should not be lifted as to Amgen given the merits of its pending motion to dismiss. Unlike virtually every other defendant, Amgen previously has not been required to amass documents relating to AWP in response to a government subpoena or other inquiry. As a result, it will be required to undertake for the first time the enormously costly and disruptive process of locating, assembling, reviewing, copying

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[1] Plaintiffs concede in the AMCC that Amgen's sale and marketing of Epogen is not reimbursed in the Medicare Part B context based upon AWP. *See* AMCC ¶ 217 n.1. Consequently, Epogen clearly does not fall within the scope of discovery. Plaintiffs also are not entitled to discovery regarding Amgen's products Enbrel and Kineret because they are self-administered drugs and thus are not reimbursed under Medicare Part B. The Court's order thus reaches three Amgen products: Aranesp, Neulasta and Neupogen. Amgen does not manufacture or distribute any multi-source or generic drugs or biologics.

and producing the vast number of documents potentially responsive to plaintiffs' anticipated requests. Taken together with the fact that Amgen's pending motion is a "likely winner," *cf. In re Lotus Development Corp. Securities Litigation*, 875 F.Supp. 48, 51 (D. Mass . 1995), ample basis exists for staying discovery until the Court has ruled on that motion.

This Court repeatedly has, in the context of this case and more generally, recognized that a defendant in Amgen's position should not be subjected to the enormous burdens of discovery unless the plaintiff can first comply with Rule 9(b). *See, e.g., U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 46 (D. Mass. 2001) (citations omitted) (Rule 9(b) services to "prevent[] conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and [to] protect[] defendants from groundless charges that may damage their reputations"); 1/13/03 Hearing Tr. at 117 (relevant portions of which are attached as Exhibit 2) (Court noting "I don't want people spending a fortune on something which may be a much pared-down case, if any. ... I don't want people to be battering back and forth on discovery at this point [during the pendency of the motions to dismiss]."). If Rule 9(b) means anything, it means that, *before* asserting a cause of action and being able to proceed with discovery, a plaintiff must have an adequate good faith basis for its claims. *See Romani v. Sharson Lehman Hutton,* 9292 F/2d 875, 877-78 (1st Cir. 1991). As to Amgen, such a basis is plainly lacking.

Amgen is one of only a handful of defendants to have been completely dismissed, by name, from the plaintiffs' Master Consolidated Complaint (the "MCC") due to the plaintiffs' failure to meet the burdens of Rule 9(b). At the January 13, 2003 hearing on the defendants' motions to dismiss the MCC, the Court presaged its later written decision,

advising the plaintiffs counsel that "[y]ou've got to particularize exactly what drugs, exactly what the fraud is, which plaintiffs paid for what drugs." Exh. 2 (1/13/03 Hearing Tr.) at 74. Consistent with that admonition, the Court made clear in its May 13, 2003 memorandum and order that the plaintiffs had failed to meet this burden in their allegations against Amgen. The Court dismissed various claims and various defendants (including all claims against Amgen) stating that, as to *each defendant*, and as to *each drug*, the plaintiffs must "clearly and concisely allege ... (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharmaceutical Indus. Avg. Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D. Mass. 2003).

Plainly, the Court's order and Rule 9(b) require more than a simple allegation that some plaintiff purchased a product, tied to a reference to the published AWP. This type of pleading cannot possibly satisfy Rule 9(b) because it *assumes* that the published AWP is fraudulent without, as Rule 9(b) and the Court's prior rulings require, articulating with particularity as to each defendant and each drug why and how this is so. Were this not the case, there would be virtually no distinction between Rule 8 notice pleading and the heightened pleading standard under Rule 9(b). Indeed, the plaintiffs themselves have conceded that Rule 9(b) requires them to allege, at a minimum, *how* the AWP was fraudulent, at least by reference to the spread between an actual price and a published AWP. *See* Exh. 2 (1/13/03 Hearing Tr.) at 103, 106. As to Amgen, they simply have not done what they at least have tacitly admitted they must.

Unable to rely on internal corporate records or government investigations in coming up with something to allege against Amgen, plaintiffs instead rely solely on an

unsupported and unsupportable "logical inference" that Amgen must have engaged in fraud because other defendants allegedly did. *See* AMCC ¶ 221.[2] Plaintiffs simply are unable to identify any particulars of *Amgen's* supposed fraud, and instead rely on allegations against others, claiming that this is enough. It is not. In fact, the Court specifically rejected precisely this kind of pleading at the September 18, 2003, hearing, unequivocally stating that the plaintiffs "can't get away with just saying they are a drug company and therefore they must be doing it." *Accord Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 877-878 (1st Cir. 1991) (Rule 9(b) requires minimally sufficient factual allegations as to each defendant).

Requiring Amgen to engage in discovery at this stage will be particularly burdensome because Amgen has not heretofore been required to search for and compile records in response to any government subpoena or other inquiry relating to AWP. Unlike most if not all of its co-defendants, Amgen will be required to undertake for the first time an enormously expensive and disruptive search for information relating to product pricing, sales and marketing practices for a number of its products, potentially spanning more than a decade. Such an undertaking will undoubtedly require thousands

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[2] The plaintiffs' core allegation against Amgen, contained in paragraph 221 of the AMCC reads, in its entirety:

> Amgen also know that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, *the competing manufacturers' manipulate the AWP* to create a reimbursement advantage for their drugs. Specifically, Amgen's Kineret competes with J&J's Remicade and Immunex's Enbrel; Neupogen competed against Immunex's Leukine; and Aranesp competes with Procrit, J&J's epoetin alfa product. *See* Amgen's 2001 Form 10-K (P002327-P002397). All of *these competing drugs are alleged herein to be subject to AWP manipulation. The logical inference is that Amgen also engaged in AWP manipulation* for those drugs where the competitors were manipulating and marketing the AWP spread.

See AMCC at ¶ 221 (emphasis added).

of man-hours, cost hundreds of thousands of dollars and prove to be a significant distraction to Amgen's business.

The tremendous burden on Amgen, particularly in light of the merits of its pending motion to dismiss, stands in stark contrast to the utter lack of any prejudice to the plaintiffs as a result of a limited continuing stay. The plaintiffs' response to Amgen's pending motion to dismiss is not affected because that briefing is complete and because the motion is based on the allegations of the AMCC and does not in any way relate to discovery. *See LTX Corp. v. Daewoo Corp.*, 979 F.Supp. 51, 65 (D. Mass. 1997). The only conceivable downside to the plaintiffs (and this assuming Amgen's motion is denied) is a brief additional delay in their ability to pursue discovery against Amgen. Given that they have proffered that they will now be permitted discovery as to some 60 or more additional drugs, plaintiffs' counsel surely will have plenty to occupy their time without pursuing discovery against Amgen for a month or so.

At bottom, the heavy burdens associated with subjecting Amgen to extensive discovery, the utter lack of prejudice to the plaintiffs resulting from a brief additional stay of discovery, and the plaintiffs' failure to satisfy Rule 9(b) in their allegations against Amgen fully support a continued stay of discovery as to Amgen until the Court has had an opportunity to rule on Amgen's pending individual motion to dismiss the AMCC.

Conclusion

For the reasons set forth herein, Amgen respectfully requests that the Court continue the limited stay of discovery as to Amgen pending the Court's consideration of, and decision on, Amgen's individual motion to dismiss the Amended Master Consolidated Complaint.

Respectfully submitted,

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Dated: December 1, 2003

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party by ~~mail~~ hand on VERILAW 12-01-03

KELLY LIBBY & HOOPES

FRANK A. LIBBY, JR.
Email: falibby@klhboston.com

December 1, 2003

BY HAND

Clerk's Office
United States Courthouse
1 Courthouse Way
Boston, MA 02210

Re: Citizens for Consumer Justice, et al v. Abbott Laboratories, et al., Civil Action No. 01-cv-12257 PBS (D. Mass.); MDL No. 1456

Dear Sir/Madam:

Enclosed for filing in the above-referenced matters, on behalf of Defendant Amgen, Inc., please find ***Motion for a Continued Limited Stay of Discovery Pending Ruling on its Individual Motion to Dismiss the AMCC.***

Please time/date stamp the enclosed copy of this letter and return it to us. Thank you for your time and attention to this matter.

Very truly yours,

Frank A. Libby, Jr.

FAL/kmk
Enclosure

cc: Joseph H. Young, Esq.